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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/519,295	10/31/2005	Jan Vandeputte	B-5626pct 622393-1	9162
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LADAS & PARRY			MERCIER, MELISSA S	
	IRE BOULEVARD, SUITE	2100		
LOS ANGEL	ES, CA 90036-5679		ART UNIT	PAPER NUMBER
			1615	

DATE MAILED: 11/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)	
	10/519,295	VANDEPUTTE, JAN	
Office Action Summary	Examiner	Art Unit	
	Melissa S. Mercier	1615	
The MAILING DATE of this communicatio Period for Reply	n appears on the cover sheet w	ith the correspondence address	
A SHORTENED STATUTORY PERIOD FOR R WHICHEVER IS LONGER, FROM THE MAILIN  - Extensions of time may be available under the provisions of 37 C after SIX (6) MONTHS from the mailing date of this communicati  - If NO period for reply is specified above, the maximum statutory  - Failure to reply within the set or extended period for reply will, by Any reply received by the Office later than three months after the earned patent term adjustment. See 37 CFR 1.704(b).	NG DATE OF THIS COMMUNI FR 1.136(a). In no event, however, may a on. period will apply and will expire SIX (6) MOI statute, cause the application to become A	CATION. reply be timely filed ITHS from the mailing date of this communication BANDONED (35 U.S.C. § 133).	
Status			
1) Responsive to communication(s) filed on		,	
2a) ☐ This action is <b>FINAL</b> . 2b) ⊠	This action is non-final.	•	
3) Since this application is in condition for all	llowance except for formal mat	ters, prosecution as to the merits is	
closed in accordance with the practice un	nder <i>Ex parte Quayle</i> , 1935 C.[	). 11, 453 O.G. 213.	·
Disposition of Claims			
4) ☐ Claim(s) 1-19 is/are pending in the applic 4a) Of the above claim(s) is/are wit 5) ☐ Claim(s) is/are allowed. 6) ☐ Claim(s) 1-19 is/are rejected. 7) ☐ Claim(s) is/are objected to. 8) ☐ Claim(s) are subject to restriction a	thdrawn from consideration.		
Application Papers			
9) The specification is objected to by the Exa  10) The drawing(s) filed on is/are: a)  Applicant may not request that any objection to Replacement drawing sheet(s) including the control of the c	accepted or b) objected to to the drawing(s) be held in abeya correction is required if the drawing	nce. See 37 CFR 1.85(a). (s) is objected to. See 37 CFR 1.121(d	<b>)</b>
Priority under 35 U.S.C. § 119			
<ul> <li>12) Acknowledgment is made of a claim for for a) All b) Some * c) None of:</li> <li>1. Certified copies of the priority docu</li> <li>2. Certified copies of the priority docu</li> <li>3. Copies of the certified copies of the application from the International B</li> <li>* See the attached detailed Office action for</li> </ul>	ments have been received. ments have been received in A e priority documents have beer tureau (PCT Rule 17.2(a)).	opplication No received in this National Stage	
Attachment(s)  1) Notice of References Cited (PTO-892)  2) Notice of Draftsperson's Patent Drawing Review (PTO-94)  3) Information Disclosure Statement(s) (PTO/SB/08)  Paper No(s)/Mail Date	(8) Paper No	Summary (PTO-413) s)/Mail Date nformal Patent Application 	

#### **DETAILED ACTION**

#### Priority

Applicants claim of priority to PCT/NL03/00451 filed on June 19, 2003 is acknowledged.

#### Information Disclosure Statement

It is noted that no Information Disclosure Statements were filed with this application.

#### Claim Objections

Claim 5 is objected to because of the following informalities: in order to fully clarify the claims, it is recommended that applicant use the terminology "further comprising" in lieu of "in addition to", when adding components. Appropriate correction is requested.

Claims 9-10 are objected to because of the following informalities: it is recommended that applicant use the terminology "wherein the acrylic monomers are selected from the group consisting of", to clarify the claim. Appropriate correction is requested.

Claim 13 is objected to because of the following informalities: in order to fully clarify the claims, it is recommended that applicant use the terminology "further comprising" when adding components. Appropriate correction is requested.

## Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2-3 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 2-3 provides for the use of healing wounds and as a cosmetic, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

# Claim Rejections - 35 USC § 101

Claims 2-3 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

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# Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3, 5, and 7-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Lundmark (US Patent 6,174,535).

Lundmark teaches, "dispersing honey in polyglycerylmethacrylate, and mixing the honey and the polyglycerylmethacrylate for a sufficient period of time to form a hydrated honey gel polymeric composition" (column 2, lines 54-56).

Regarding Claim 3, Lundmark discloses, "the products of the present invention may be formulated into lotions, shampoos, hair conditioners, sunscreens, insect repellants and the like" (column 4, lines 60-63).

Regarding Claim 5, Lundmark discloses, "a desirable component for use herein is a glycol. The glycol adds humectant properties to the composition" (column 4, lines 18-20).

Regarding Claim 7, Lundmark discloses, "the preferred polyglycerylmethacrylate is Lubrajel CG, a registered trademark of United Guardian Inc. Lubrajel CG is a clathrate formed by the reaction of glycerin and methylmethacrylate" (column 3, lines 11-24). The presence of glycerin would exhibit the humectant qualities claimed in the instant claim.

Regarding Claim 8, Lundmarks Example II discloses 3 formulations of their composition, each comprising between 26.00% and 29.00% honey (column 5, line 18).

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Regarding Claims 15-16, the prior art is silent as to the peroxide number of honey and the LPS content. It is the examiners position that these properties are inherent properties of honey and therefore, would be present in the prior art teachings.

### Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

- 1. Determining the scope and contents of the prior art.
- 2. Ascertaining the differences between the prior art and the claims at issue.
- 3. Resolving the level of ordinary skill in the pertinent art.
- 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-2, 7, 9-10, 12, and 19, rejected under 35 U.S.C. 103(a) as being unpatentable over Lundmark (US Patent 6,174,535) in view of Stout (US Patent 4,671,267).

Lundmark's teachings as they apply to Claim 1 are described above.

Lundmark does not disclose the composition can be used for the healing of wounds, the use of glycerin as a humectant, the thickness of the application of the composition, and the gel being a 50% acrylamide, 50% water mixture.

Regarding Claims 2, 7, and 9, Stout discloses, "improved therapy members useful for treating of sprains, muscle aches, orthopedic and skin injuries such as burns and other wounds are provided which make use of a pliable, self-sustaining, moisture sorbing gel including a humectant such as glycerin entrapped within a synthetic resin polymer matrix (e.g., a matrix containing acrylic acid or acrylamide monomer moieties)" (abstract). Stout further discloses, "the gel material can be applied directly to injured skin to in effect create a temporary skin with ideal air permeability" (abstract).

Regarding Claim 12, Stout discloses in Table II and Example 4, a 50% acrylamide in water solution. The examiner is interpreting this to be a mixture that is 50% acrylamide and 50% water.

Regarding Claim 19, Stout discloses, "the preferred gel material provides an excellent dressing for the treatment of burned or otherwise injured skin. In this case a thin (for example from about 0.05 to 0.5 inches) layer of the gel material is hermetically sealed in a sterile package, and in use is simply directly applied to injured skin, without any intermediate cloth covering or the like" (column 3, lines 24-45). 0.05 to 0.5 inches converts to approximately, 1.27mm to 12.7mm, which overlaps the claimed range.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to have combined the teaching of Lundmark with the teachings of Stout in order to form 'a gel material that can be applied directly to injured skin to in effect create a temporary skin with ideal air permeability. Furthermore, the moisture absorbing and desorbing properties of the gel create a moisture equilibrium between the gel, damaged skin and the atmosphere, thus promoting rapid healing" (abstract).

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Claims 1, 4 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lundmark (US Patent 6,174,535).

Lundmark's teachings as they apply to Claim 1 are described above.

Lundmark does not disclose a composition with the exact ranges specified by the instant claims. However, according to MPEP 2144.05 II A Optimization within Prior Art Conditions or Through Routine Experimentation, differences in concentration will not support the patentability of subject matter encompasses by the prior art unless there is evidence indicating such concentrations are critical. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. "The normal desire of scientist or artisans to improve upon what is already generally known provides the motivation to determine where the disclosed set of percentage ranges is the optimum combination of percentages." (Peterson, 315 F.3d at 1330, 65 USPQ2d at 1382).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to have expanded upon the teachings of Lundmark to make a composition with the desired qualities of skin care compositions, including tackiness, texture, and spread ability. It would be within the knowledge of a person of ordinary skill in this art to arrive at the desired qualities through routine experimentation.

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Claims 1 and 10-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lundmark (US Patent 6,174,535) in view of in view of Stout (US Patent 4,671,267) and further in view of Dell (US Patent 4,542,012).

Lundmark's teachings as they apply to Claim 1 are described above.

Lundmark does not disclose the use of acrylamide or analog compounds consisting of diacetone acrylamide, vinyllactam, N-alkylated acrylamide, N,N-diakylated acrylamide, N-vinylpyrrolidone, or acryloylmorpholin.

Stout teaches the use of acrylamide as a monomer, however, Stout does not teach the use of analog compounds.

Dell discloses, "a dermatologically acceptable, film-forming composition which comprises a film-forming polymer and, as a broad spectrum antimicrobial agent. The compositions when applied to the skin from a fugitive solvent form a substantially water-insoluble, tack-free, flexible film, which adheres to the skin, releases the antimicrobial agent. (abstract).

Dell disclosed the polymer being "a polyvinylpyrrolidone polymer which is the free-radical-polymerization reaction product of at least N-vinylpyrrolidone and a vinyl-functional compound" (column 2, lines 43-47).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to have expanded upon the teachings of Lundmark and Stout, with the polymer taught by Dell, in order to form "a good film-forming composition should be dermatologically-acceptable and capable of application to skin conveniently as a solution in a dermatologically-acceptable, volatile solvent. The film resulting from

application of such a solution should be bacteria-impermeable, water-insoluble, nontacky and should permit facile transmission of water vapor there through. It should adhere suitably to skin and be capable of releasing the antimicrobial agent onto the skin over a period of time to promote asepsis for a suitably long period of time" (column 2, lines 3-24).

The Applicant would have a reason expectation of success since N-vinylpyrrolidone is commonly used as a film-forming polymer in cosmetic formulations. It would be within the knowledge of one of ordinary skill in the art to substitute it for an acrylic polymer used for the same function.

Claims 1, 13-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lundmark (US Patent 6,174,535) in view of Trenzeluk (US Patent 4,857,328).

Lundmark's teachings as they apply to Claim 1 are described above.

Lundmark does not disclose the use of antioxidants, transretinoic acid and/or derivatives and precursors thereof, polyunsaturated fatty acids, n-hexacosanol, bis(maltolato)oxo-vanadium(IV), aloe vera, and thickeners. Lundmark also does not disclose a percentage of additives.

Trenzeluk discloses "a skin therapeutic mixture is useful for the alleviation of certain skin disorders such as acne, psoriasis, burns, pimples, blackheads, and open sores: the therapeutic agent being the extract from the dried leaves of the aloe vera plant; the skin therapeutic mixture comprises about 7.4% by weight of the extract from the dried leaves of the aloe vera plant as the therapeutic agent" (abstract).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to have added aloe vera to a skin care composition, since aloe is well known in the art for its soothing effects, fragrance, and healing qualities.

The applicant would have a reason expectation of success since the use of aloe vera is well known in the art for the same reasons and qualities applicant is claiming.

Claims 1 and 17-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lundmark (US Patent 6,174,535) in view of Hymes et al. (US Patent 4,307,717).

Lundmark's teachings as they apply to Claim 1 are described above.

Lundmark does not disclose the honey being sterilized with the use of gamma rays.

Hymes discloses a liquid absorbent, adhesive bandage, in which the combination of the mixture is then subjected to irradiation (usually gamma rays) usually to 2.5 mega rads for sterilization (column 2, lines 65-67).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to have used the sterilization method taught by Hymes on the composition taught by Lundmark in order to make a composition which is suitable for direct contact with the skin to cover surgical wounds or burn tissue" (Hymes, column 2, lines 23-27).

Applicant would have a reasonable expectation of success in the sterilization of a composition using gamma rays, since irradiation with gamma raise is known in the art as being effective.

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# Conclusion

No claims are allowable. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melissa S. Mercier whose telephone number is (571) 272-9039. The examiner can normally be reached on 7:30am-4pm Mon through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

**MSMercier** 

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